



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/559,707      | 04/27/2000  | John Greenwood       | 19141-002           | 2553             |

7590 06/07/2002

Ivor R Elrifi  
C/O Mintz Levin  
One Financial Center  
Boston, MA 02111

EXAMINER

LOEB, BRONWEN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1636

15

DATE MAILED: 06/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/559,707

Applicant(s)

GREENWOOD ET AL.

Examin r

Bronwen M. Loeb

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,10,24 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,10 and 24 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/973,553.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to the after-final amendment filed 20 May 2002 in which claims 1, 10, 24 and 37 were amended. This amendment has been entered.

The finality of the previous action is withdrawn in view of the newly discovered reference(s) to Tao et al (USP 6,361,771). Rejections based on the newly cited reference(s) follow.

Claims 1, 10, 24 and 37 are pending.

### ***Claim Objections***

1. Claims 24 and 37 are objected to because of the following informalities:

In amended claim 24, the phrase "the cells of" in line 3 should be deleted as the Markush group recites cell lines.

In claim 37, the word "Institut" is misspelled as "Insitute".

Appropriate correction is required.

### ***Response to Amendment***

2. The rejection of claim 24 under 35 USC §112, first paragraph for scope of enablement for reasons of record has been withdrawn in view of Applicant's amendment.

The rejection of claims 1, 10 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of Applicant's amendment.

Art Unit: 1636

The rejection of claims 1 and 24 under 35 U.S.C. §103(a) as being unpatentable over Dunn et al (Invest Ophthalmol Vis Sci (1998) 39:2744-2749) has been withdrawn in view of Applicant's amendment.

3. Claim 10 stands rejected under 35 USC §112, first paragraph for lack of enablement for reasons of record and as further discussed below.

4. New grounds of rejection are presented below.

### ***Response to Arguments***

5. With regard to the rejection of claim 10 under 35 USC §112, first paragraph, Applicant states that they will deposit the recited cell lines upon indication of allowable subject matter. The rejection stands until Applicant deposits the cell lines or makes a statement that such deposits will be made in accordance with 37 CFR §1.803. See MPEP §2411.02.

### **New Grounds of Rejection**

#### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1636

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,361,771 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because an ARPE-19 cell line transformed to express one of BDNF, NT-4, CNTG, Axokine, IGF I or II, TGF $\beta$ -II, Midkine, IL-1 $\beta$ , TNF, NGF, IL-2/3, ILFD, IL-6, NTN, Neublastin, VEGF, GDNF, PDGF, LEDGF or PEDF, which is one embodiment of claim 1, is essentially generic to claim 7 of USP 6,361,771 B1 which claims such a cell line with a semipermeable membrane.

8. Claim 1 is directed to an invention not patentably distinct from claim 7 of commonly assigned US Patent No. 6,361,771 B1. Specifically, an ARPE-19 cell line transformed to express one of BDNF, NT-4, CNTG, Axokine, IGF I or II, TGF $\beta$ -II, Midkine, IL-1 $\beta$ , TNF, NGF, IL-2/3, ILFD, IL-6, NTN, Neublastin, VEGF, GDNF, PDGF, LEDGF or PEDF, which is one embodiment of claim 1, is essentially generic to claim 7 of USP 6,361,771 B1 which claims such a cell line with a semipermeable membrane.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US Patent No. 6,361,771 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this

Art Unit: 1636

application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Art Unit: 1636

10. Claims 1 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Tao et al (USP 6,361,771 B1). Tao et al teach ARPE-19 comprising an expression vector coding for one of the following polypeptides: BDNF, NT-4, CNTG, Axokine, IGF I or II, TGF $\beta$ -II, Midkine, IL-1 $\beta$ , TNF, NGF, IL-2/3, ILFD, IL-6, NTN, Neublastin, VEGF, GDNF, PDGF, LEDGF or PEDF. The polypeptides may be expressed in vitro by incubating the transformed ARPE-19 cells in appropriate medium. See entire document, especially col. 7, line 50-col. 8, line 65; col. 20, line 4-col. 22, line 10; and claim 7.

### ***Conclusion***

Claims 1, 10 and 24 are rejected. Claims 10 and 37 are free of prior art. Claim 37 is objected to but would be allowable if the objection were overcome.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Application/Control Number: 09/559,707  
Art Unit: 1636

Page 7

Bronwen M. Loeb, Ph.D.  
Patent Examiner  
Art Unit 1636

June 6, 2002



**REMY YUCEL, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**